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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED, and
ASTRAZENECA AB,

Plaintiffs,

v.

SANDOZ, INC., SAGENT
PHARMACEUTICALS, INC., and
GLENMARK PHARMACEUTICALS INC.,
USA,

Defendants.

Consolidated Case No. 1:14-CV-03547-RMB-
KMW

**PLAINTIFFS' ANSWER TO DEFENDANT SAGENT PHARMACEUTICALS, INC.'S
COUNTERCLAIMS**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca"), by and through their undersigned counsel, hereby respond to Defendant Sagent Pharmaceuticals, Inc.'s ("Sagent") Counterclaims as follows:

PARTIES

1. Upon information and belief, AstraZeneca admits the allegations of Paragraph 1.
2. AstraZeneca admits the allegations of Paragraph 2.
3. AstraZeneca admits the allegations of Paragraph 3.
4. AstraZeneca admits the allegations of Paragraph 4.

JURISDICTION AND VENUE

5. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-4 as if fully stated herein.
6. Paragraph 6 states a legal conclusion to which no response is required.
7. Paragraph 7 states a legal conclusion to which no response is required.
AstraZeneca denies that this Court has subject matter jurisdiction over Sagent's counterclaims as to the '160 patent because that patent is no longer alleged to be infringed in this litigation.
8. Paragraph 8 states a legal conclusion to which no response is required.
AstraZeneca denies that this Court has subject matter jurisdiction over Sagent's counterclaims as to the '160 patent because that patent is no longer alleged to be infringed in this litigation.
9. AstraZeneca admits, for purposes of this action only, that venue is proper in this Court.
10. Paragraph 10 states a legal conclusion to which no response is required.
To the extent a response is required, AstraZeneca admits that it is subject to personal jurisdiction in this jurisdiction for purposes of this litigation.

COUNT I

(Declaratory Judgment of Non-Infringement of the '122 patent)

11. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-10 as if fully stated herein.

12. AstraZeneca admits that AstraZeneca AB is the legal owner of the '122 patent, and that AstraZeneca UK Limited is the beneficial owner of the '122 patent. AstraZeneca further admits that it sued Sagent for infringement of one or more claims of the '122 patent in the present action. AstraZeneca denies all other allegations in Paragraph 12.

13. Paragraph 13 states a legal conclusion to which no response is required.

14. AstraZeneca denies the allegations of Paragraph 14.

15. AstraZeneca denies the allegations of Paragraph 15.

COUNT II

(Declaratory Judgment of Invalidity of the '122 patent)

16. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-15 as if fully stated herein.

17. Paragraph 17 states a legal conclusion to which no response is required.

18. AstraZeneca denies the allegations of Paragraph 18.

19. AstraZeneca denies the allegations of Paragraph 19.

COUNT III

(Declaratory Judgment of Non-Infringement of the '160 patent)

20. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-19 as if fully stated herein.

21. AstraZeneca admits that AstraZeneca AB is the legal owner of the '160 patent, and that AstraZeneca UK Limited is the beneficial owner of the '160 patent. AstraZeneca further admits that it sued Sagent for infringement of one or more claims of the '160 patent in the present action, but no longer asserts those claims. AstraZeneca denies all other allegations in Paragraph 21.

22. Paragraph 22 states a legal conclusion to which no response is required.

23. AstraZeneca denies the allegations of Paragraph 23.

24. AstraZeneca denies the allegations of Paragraph 24.

COUNT IV

(Declaratory Judgment of Invalidity of the '160 patent)

25. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-24 as if fully stated herein.

26. Paragraph 26 states a legal conclusion to which no response is required.

27. AstraZeneca denies the allegations of Paragraph 27.

28. AstraZeneca denies the allegations of Paragraph 28.

COUNT V

(Declaratory Judgment of Non-Infringement of the '680 patent)

29. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-28 as if fully stated herein.

30. AstraZeneca admits that AstraZeneca AB is the legal owner of the '680 patent, and that AstraZeneca UK Limited is the beneficial owner of the '680 patent. AstraZeneca further admits that it sued Sagent for infringement of one or more claims of the '680 patent in the present action. AstraZeneca denies all other allegations in Paragraph 30.

- 31. Paragraph 31 states a legal conclusion to which no response is required.
- 32. AstraZeneca denies the allegations of Paragraph 32.
- 33. AstraZeneca denies the allegations of Paragraph 33.

COUNT VI

(Declaratory Judgment of Invalidity of the '680 patent)

34. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-33 as if fully stated herein.

- 35. Paragraph 35 states a legal conclusion to which no response is required.
- 36. AstraZeneca denies the allegations of Paragraph 36.
- 37. AstraZeneca denies the allegations of Paragraph 37.

COUNT VII

(Declaratory Judgment of Non-Infringement of the '139 patent)

38. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-37 as if fully stated herein.

39. AstraZeneca admits that AstraZeneca AB is the legal owner of the '139 patent, and that AstraZeneca UK Limited is the beneficial owner of the '139 patent. AstraZeneca further admits that it sued Sagent for infringement of one or more claims of the '139 patent in the present action. AstraZeneca denies all other allegations in Paragraph 39.

- 40. Paragraph 40 states a legal conclusion to which no response is required.
- 41. AstraZeneca denies the allegations of Paragraph 41.
- 42. AstraZeneca denies the allegations of Paragraph 42.

COUNT VIII

(Declaratory Judgment of Invalidity of the '139 patent)

43. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-42 as if fully stated herein.

44. Paragraph 44 states a legal conclusion to which no response is required.

45. AstraZeneca denies the allegations of Paragraph 45.

46. AstraZeneca denies the allegations of Paragraph 46.

COUNT IX

(U.S. Patent No. 6,774,122 Is Not Unenforceable)

47. AstraZeneca restates and incorporates by reference its responses to Paragraphs 1-46 as if fully stated herein. AstraZeneca further responds to paragraphs 1-160 of Sagent's Seventh Affirmative Defense, as follows:

1. AstraZeneca denies the allegations of paragraph 1 of the Seventh Affirmative Defense.
2. AstraZeneca admits the allegations in paragraph 2 of the Seventh Affirmative Defense.
3. AstraZeneca admits the allegations in paragraph 3 of the Seventh Affirmative Defense.
4. AstraZeneca admits the allegations in paragraph 4 of the Seventh Affirmative Defense.
5. AstraZeneca admits the allegations in paragraph 5 of the Seventh Affirmative Defense.

6. AstraZeneca admits that Sagent refers collectively to the '122 Patent, the '160 Patent, the '680 Patent, and the '139 Patent as the "Patents-in-Suit" but denies that all four patents continue to be asserted in this litigation and, therefore, denies the remaining allegations in paragraph 6 of the Seventh Affirmative Defense.
7. AstraZeneca admits the allegations of paragraph 7 of the Seventh Affirmative Defense.
8. AstraZeneca admits that there are similarities in the specifications of the Patents-in-Suit. AstraZeneca denies the remaining allegations in paragraph 8 of the Seventh Affirmative Defense.
9. AstraZeneca admits that Claim 1 of the '122 Patent recites, among other limitations, a method of treating "a hormonal dependent benign or malignant disease of the breast or reproductive tract" using specified formulations of fulvestrant, including, for example, a formulation of fulvestrant containing "10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of castor oil vehicle." AstraZeneca further admits that Sagent refers to some of the limitations of Claim 1 as the "Claimed 10/10/15 Formulation". AstraZeneca denies the remaining allegations of paragraph 9 of the Seventh Affirmative Defense.

10. AstraZeneca denies the allegations of paragraph 10 of the Seventh Affirmative Defense.
11. AstraZeneca denies the allegations of paragraph 11 of the Seventh Affirmative Defense.
12. AstraZeneca denies the allegations of paragraph 12 of the Seventh Affirmative Defense.
13. AstraZeneca denies the allegations of paragraph 13 of the Seventh Affirmative Defense.
14. AstraZeneca denies the allegations of paragraph 14 of the Seventh Affirmative Defense.
15. AstraZeneca admits that the publication Sandra W. McLeskey et al., Tamoxifen-resistant Fibroblast Growth Factor-transfected MCF-7 Cells Are Cross-resistant in Vivo to the Antiestrogen ICI 182,780 and Two Aromatase Inhibitors, 4 CLINICAL CANCER RES. 697 (1998) (“the 1998 McLeskey Publication”) was listed among the 767 references identified in the bibliography to the New Drug Application (“NDA”) for FASLODEX[®]. AstraZeneca denies the remaining allegations of paragraph 15 of the Seventh Affirmative Defense.
16. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this

reference. AstraZeneca denies the remaining allegations of paragraph 16 of the Seventh Affirmative Defense.

17. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this reference. AstraZeneca denies the remaining allegations of paragraph 17 of the Seventh Affirmative Defense.
18. AstraZeneca denies the allegations of paragraph 18 of the Seventh Affirmative Defense.
19. AstraZeneca denies the allegations of paragraph 19 of the Seventh Affirmative Defense.
20. AstraZeneca admits that it is a global, science-led, biopharmaceutical company, with a focus on developing medicines across a number of therapeutic areas, including the area of oncology. AstraZeneca further admits that FASLODEX[®], IRESSA[®] and ZOLADEX[®] are three of its oncological drugs. AstraZeneca denies the remaining allegations of paragraph 20 of the Seventh Affirmative Defense.
21. AstraZeneca admits that it is the holder of NDA No. 21344, directed to FASLODEX[®], which was approved by FDA on April 25, 2002. AstraZeneca denies the remaining allegations of paragraph 21 of the Seventh Affirmative Defense.

22. AstraZeneca admits that Sagent attaches as Exhibit 3 a document that it alleges to be a copy of the FASLODEX[®] label and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 22 of the Seventh Affirmative Defense.
23. Upon information and belief, AstraZeneca states that no ANDA product, for which the Reference Listed Drug is FASLODEX[®], has been approved by FDA. AstraZeneca denies the remaining allegations of paragraph 23 of the Seventh Affirmative Defense.
24. AstraZeneca admits that Sagent attaches as Exhibit 1 a document that it alleges to be a copy of the AstraZeneca 2014 Annual Report and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 24 of the Seventh Affirmative Defense.
25. AstraZeneca admits that Sagent attaches as Exhibit 4 a document having the title “Annual Worldwide Faslodex Sales from AstraZeneca's Annual Reports” and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 25 of the Seventh Affirmative Defense.
26. AstraZeneca admits that the active pharmaceutical ingredient in FASLODEX[®] is fulvestrant, also known by the chemical name,

7 α -[9-(4,4,5,5,5-pentafluoropentylsulphanyl) nonyl]oestra-
1.3.5(10)-triene-3,17 β -diol.

27. AstraZeneca admits that U.S. Patent No. 4,659,516 (“the ’516 patent”) was assigned to Imperial Chemical Industries PLC, a predecessor of AstraZeneca. Paragraph 27 states a legal conclusion as to the scope of that patent to which no response is required. AstraZeneca also admits that Sagent attaches as Exhibit 6 a document that it alleges to be a copy of a Certificate Extending Patent Term relating to the ’516 patent and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 27 of the Seventh Affirmative Defense.
28. AstraZeneca denies the allegations of paragraph 28 of the Seventh Affirmative Defense.
29. AstraZeneca denies the allegations of paragraph 29 of the Seventh Affirmative Defense.
30. AstraZeneca denies the allegations of paragraph 30 of the Seventh Affirmative Defense.
31. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31 of the Seventh Affirmative Defense, and therefore denies them.
32. AstraZeneca admits that Sagent attaches as Exhibit 6 a document that it alleges to be a copy of a Certificate Extending Patent Term

relating to the '516 patent and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 32 of the Seventh Affirmative Defense.

33. AstraZeneca denies the allegations of paragraph 33 of the Seventh Affirmative Defense.

34. AstraZeneca admits that the active pharmaceutical ingredient in FASLODEX[®] is fulvestrant. AstraZeneca further admits that development of fulvestrant, and other novel chemical compounds, began at Imperial Chemical Industries ("ICI"), a predecessor of AstraZeneca, and that fulvestrant was designated as "ICI 182,780." AstraZeneca denies the remaining allegations of paragraph 34 of the Seventh Affirmative Defense.

35. AstraZeneca admits that Sagent attaches as Exhibit 5 a document that it alleges to be a copy of the '516 patent and further states that the document to which Sagent refers speaks for itself. AstraZeneca further admits that the application that issued as the '516 patent was filed on or around October 1, 1984, and the '516 patent was granted on or around April 21, 1987. Paragraph 35 of the Seventh Affirmative Defense states a legal conclusion as to the scope of that patent to which no response is required. AstraZeneca denies the remaining allegations of paragraph 35 of the Seventh Affirmative Defense.

36. AstraZeneca admits that Sagent attaches as Exhibit 5 a document that it alleges to be a copy of the '516 patent and further states that the document to which Sagent refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 36 of the Seventh Affirmative Defense.
37. AstraZeneca admits that work to develop formulations of fulvestrant continued following the grant of the '516 patent. AstraZeneca further admits that Sagent attaches as Exhibit 9 a document that it alleges to be a copy of an ICI Research Meeting Report and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the remaining allegations of paragraph 37 of the Seventh Affirmative Defense.
38. AstraZeneca admits that Sagent attaches as Exhibits 10 and 11 documents that it alleges to be copies of Formulation Research Team Research Reports and further states that the paragraph mischaracterizes the documents to which it refers, which documents speaks for themselves. AstraZeneca denies the remaining allegations of paragraph 38 of the Seventh Affirmative Defense.
39. AstraZeneca admits that Sagent attaches as Exhibit 12 a document that it alleges to be a copy of a Formulation Research Team Research Report and further states that the paragraph

mischaracterizes the document to which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 39 of the Seventh Affirmative Defense.

40. AstraZeneca denies the allegations of paragraph 40 of the Seventh Affirmative Defense.

41. AstraZeneca denies the allegations of paragraph 41 of the Seventh Affirmative Defense.

42. AstraZeneca admits that extensive *in vivo* and *in vitro* testing in animals of an extended release formulation of fulvestrant was conducted, followed by clinical trials of the formulation.

AstraZeneca denies the remaining allegations of paragraph 42 of the Seventh Affirmative Defense.

43. AstraZeneca denies the allegations of paragraph 43 of the Seventh Affirmative Defense.

44. AstraZeneca admits that Sagent attaches as Exhibit 19 a document that it alleges to be a copy of Minutes of ICI 182,780 Development Team Meeting and states that the paragraph mischaracterizes the document to which it refers, which document speaks for itself.

AstraZeneca denies the remaining allegations of paragraph 44 of the Seventh Affirmative Defense.

45. AstraZeneca admits that Sagent attaches as Exhibits 20-22 documents that it alleges to be copies of Minutes of ICI 182,780 Strategy Team Meeting and further states that the paragraph

mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the remaining allegations of paragraph 45 of the Seventh Affirmative Defense.

46. AstraZeneca admits that Sagent attaches as Exhibits 23-25 documents that it alleges to be copies of Minutes of ICI 182,780 Operational Team Meeting and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the remaining allegations of paragraph 46 of the Seventh Affirmative Defense.

47. AstraZeneca admits that Sagent attaches as Exhibits 26-28 documents that it alleges to be copies of Minutes of Faslodex Product Team Meeting and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the remaining allegations of paragraph 47 of the Seventh Affirmative Defense.

48. AstraZeneca admits that Sagent attaches as Exhibits 29-31 documents that it alleges to be copies of Emails re: Faslodex Delivery Team and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the

remaining allegations of paragraph 48 of the Seventh Affirmative Defense.

49. AstraZeneca denies the allegations of paragraph 49 of the Seventh Affirmative Defense.

50. AstraZeneca admits that samples of fulvestrant were provided to Dr. Francis Kern and Dr. Sandra McLeskey of the Georgetown Lombardi Cancer Center pursuant to appropriate confidentiality obligations. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 50 of the Seventh Affirmative Defense, and therefore denies them.

51. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 51 of the Seventh Affirmative Defense, and therefore denies them.

52. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 52 of the Seventh Affirmative Defense, and therefore denies them.

53. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 53 of the Seventh Affirmative Defense and therefore denies them.

54. AstraZeneca admits that Sagent attaches as Exhibit 33 a document that it alleges to be a copy of a Service Sample Req. Team and further states that the paragraph mischaracterizes the document to

which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 54 of the Seventh Affirmative Defense.

55. AstraZeneca denies the allegations of paragraph 55 of the Seventh Affirmative Defense.
56. AstraZeneca admits that Sagent attaches as Exhibit 8 a copy of a document that it alleges to be a copy of an IDS (the “Second IDS”) submitted in connection with the prosecution of one or more of the patents-in-suit and further states that the document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 56 of the Seventh Affirmative Defense, and specifically denies that any of the statements included in the Second IDS were false.
57. AstraZeneca denies the allegations of paragraph 57 of the Seventh Affirmative Defense.
58. AstraZeneca admits that formulated versions of fulvestrant were provided to other researchers in the United States, all pursuant to appropriate confidentiality obligations. AstraZeneca denies the remaining allegations of paragraph 58 of the Seventh Affirmative Defense.
59. AstraZeneca denies the allegations of paragraph 59 of the Seventh Affirmative Defense.
60. AstraZeneca denies the allegations of paragraph 60 of the Seventh Affirmative Defense.

61. AstraZeneca denies the allegations of paragraph 61 of the Seventh Affirmative Defense.
62. AstraZeneca denies the allegations of paragraph 62 of the Seventh Affirmative Defense.
63. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 63 of the Seventh Affirmative Defense.
64. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 64 of the Seventh Affirmative Defense.
65. AstraZeneca admits that Sagent attaches as Exhibit 51 a document that it alleges to be a copy of ICI 182,780 Collected Monthly Reports and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for themselves. AstraZeneca denies the remaining allegations of paragraph 65 of the Seventh Affirmative Defense.
66. AstraZeneca admits that Sagent attaches as Exhibit 51 a document that it alleges to be a copy of ICI 182,780 Collected Monthly Reports and further states that the paragraph mischaracterizes the documents to which it refers, which documents speak for

themselves. AstraZeneca denies the remaining allegations of paragraph 66 of the Seventh Affirmative Defense.

67. AstraZeneca admits that Sagent attaches as Exhibit 15 a document that it alleges to be a copy of ICI 182,780 Worldwide Operating Plan and further states that the paragraph mischaracterizes the document to which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 67 of the Seventh Affirmative Defense.

68. AstraZeneca admits that Sagent attaches as Exhibit 16 a document that it alleges to be a copy of a Memo re: ICI 182,780 Clinical Operating Plan and further states that the paragraph mischaracterizes the document to which it refers, which document speaks for itself. AstraZeneca denies the allegations of paragraph 68 of the Seventh Affirmative Defense.

69. AstraZeneca denies the allegations of paragraph 69 of the Seventh Affirmative Defense.

70. AstraZeneca denies the allegations of paragraph 70 of the Seventh Affirmative Defense.

71. AstraZeneca admits that NDA No. 21344, directed to FASLODEX[®], was filed with the FDA on December 6, 1996 and clinical testing in humans commenced in the United States as of January 5, 1997. AstraZeneca denies the remaining allegations of paragraph 71 of the Seventh Affirmative Defense.

- 72. AstraZeneca denies the allegations of paragraph 72 of the Seventh Affirmative Defense.
- 73. AstraZeneca denies the allegations of paragraph 73 of the Seventh Affirmative Defense.
- 74. AstraZeneca denies the allegations of paragraph 74 of the Seventh Affirmative Defense.
- 75. AstraZeneca denies the allegations of paragraph 75 of the Seventh Affirmative Defense.
- 76. AstraZeneca denies the allegations of paragraph 76 of the Seventh Affirmative Defense.
- 77. AstraZeneca denies the allegations of paragraph 77 of the Seventh Affirmative Defense.
- 78. AstraZeneca denies the allegations of paragraph 78 of the Seventh Affirmative Defense.
- 79. AstraZeneca denies the allegations of paragraph 79 of the Seventh Affirmative Defense.
- 80. AstraZeneca denies the allegations of paragraph 80 of the Seventh Affirmative Defense.
- 81. AstraZeneca denies the allegations of paragraph 81 of the Seventh Affirmative Defense.
- 82. AstraZeneca denies the allegations of paragraph 82 of the Seventh Affirmative Defense.

83. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 83 of the Seventh Affirmative Defense and therefore denies them.
84. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 84 of the Seventh Affirmative Defense and therefore denies them.
85. AstraZeneca admits that Sagent attaches as Exhibit 54 a document that it alleges to be a copy of the 1998 McLeskey Publication and further states that the document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 85 of the Seventh Affirmative Defense.
86. AstraZeneca denies the allegations of paragraph 86 of the Seventh Affirmative Defense.
87. AstraZeneca denies the allegations of paragraph 87 of the Seventh Affirmative Defense.
88. AstraZeneca admits that the '122 Patent issued on or about August 10, 2004 from U.S. Application No. 09/756,291, which was filed on January 9, 2001. AstraZeneca denies the remaining allegations of paragraph 88 of the Seventh Affirmative Defense.
89. AstraZeneca admits that the NDA for FASLODEX[®] was prepared by AstraZeneca and includes a bibliography identifying 767 references relating to fulvestrant and/or the subject matter of the

NDA. AstraZeneca denies the remaining allegations of paragraph 89 of the Seventh Affirmative Defense.

90. AstraZeneca admits that the 1998 McLeskey Publication was listed among the 767 references identified in the bibliography to the NDA for FASLODEX[®] and that the bibliography was submitted to the FDA as part of the FASLODEX[®] NDA. AstraZeneca denies the remaining allegations of paragraph 90 of the Seventh Affirmative Defense.

91. AstraZeneca denies the allegations of paragraph 91 of the Seventh Affirmative Defense.

92. AstraZeneca admits that NDA for FASLODEX[®] and the '291 application describe similar subject matter as they both relate to the same pharmaceutical compound. AstraZeneca denies the remaining allegations of paragraph 92 of the Seventh Affirmative Defense.

93. AstraZeneca denies the allegations of paragraph 93 of the Seventh Affirmative Defense.

94. AstraZeneca denies the allegations of paragraph 94 of the Seventh Affirmative Defense.

95. AstraZeneca admits that Sagent attaches as Exhibit 17 a document that it alleges to be a copy of an email to Alan Wakeling and Allen Giles, among others, and further states that the document speaks

for itself. AstraZeneca denies the remaining allegations of paragraph 95 of the Seventh Affirmative Defense.

96. AstraZeneca admits that Sagent attaches as Exhibit 18 a document that it alleges to be a copy of Faslodex FDA Letter and further states that the paragraph mischaracterizes the document to which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 96 of the Seventh Affirmative Defense.

97. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 97 of the Seventh Affirmative Defense.

98. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 98 of the Seventh Affirmative Defense.

99. AstraZeneca denies the allegations of paragraph 99 of the Seventh Affirmative Defense.

100. AstraZeneca denies the allegations of paragraph 100 of the Seventh Affirmative Defense.

101. AstraZeneca admits that nine of the 767 references identified in the bibliography of the NDA for Faslodex® were also disclosed in the prosecution of one or more of the patents-in-suit. AstraZeneca

denies the remaining allegations of paragraph 101 of the Seventh Affirmative Defense.

102. AstraZeneca denies the allegations of paragraph 102 of the Seventh Affirmative Defense.

103. AstraZeneca admits that a “Second Information Disclosure Statement” was filed during the prosecution of the application that issued as the ’122 Patent.

104. AstraZeneca admits that a “Second Information Disclosure Statement” was filed during the prosecution of the application that issued as the ’160 Patent.

105. AstraZeneca admits that a “Second Information Disclosure Statement” was filed during the prosecution of the application that issued as the ’680 Patent.

106. AstraZeneca denies the allegations of paragraph 106 of the Seventh Affirmative Defense.

107. AstraZeneca admits that Sagent attaches as Exhibit 8 a document that it alleges to be a copy of the Second IDS, and further states that the document to which the paragraph refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 107 of the Seventh Affirmative Defense.

108. AstraZeneca admits that Sagent attaches as Exhibit 8 a document that it alleges to be a copy of the Second IDS, and further states that the document to which the paragraph refers speaks for itself.

AstraZeneca denies the remaining allegations of paragraph 108 of the Seventh Affirmative Defense.

109. AstraZeneca admits that Sagent attaches as Exhibit 8 a document that it alleges to be a copy of the Second IDS, and further states that the document to which the paragraph refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 109 of the Seventh Affirmative Defense.

110. AstraZeneca admits that Sagent attaches as Exhibit 8 a document that it alleges to be a copy of the Second IDS, and further states that the document to which the paragraph refers speaks for itself. AstraZeneca denies the remaining allegations of paragraph 110 of the Seventh Affirmative Defense.

111. AstraZeneca denies the allegations of paragraph 111 of the Seventh Affirmative Defense.

112. AstraZeneca denies the allegations of paragraph 112 of the Seventh Affirmative Defense.

113. AstraZeneca denies the allegations of paragraph 113 of the Seventh Affirmative Defense.

114. AstraZeneca denies the allegations of paragraph 114 of the Seventh Affirmative Defense.

115. AstraZeneca denies the allegations of paragraph 115 of the Seventh Affirmative Defense.

116. AstraZeneca denies the allegations of paragraph 116 of the Seventh Affirmative Defense.
117. AstraZeneca denies the allegations of paragraph 117 of the Seventh Affirmative Defense.
118. AstraZeneca denies the allegations of paragraph 118 of the Seventh Affirmative Defense.
119. AstraZeneca denies the allegations of paragraph 119 of the Seventh Affirmative Defense.
120. AstraZeneca admits that Sagent attaches as Exhibit 32 excerpts of the deposition transcript of Dr. McLeskey, and further states that the paragraph mischaracterizes the testimony to which it refers, which testimony speaks for itself. AstraZeneca denies the remaining allegations of paragraph 120 of the Seventh Affirmative Defense.
121. AstraZeneca admits that Sagent attaches as Exhibit 34 excerpts of the deposition transcript of Dr. Kern, and further states that the paragraph mischaracterizes the testimony to which it refers, which testimony speaks for itself. AstraZeneca denies the remaining allegations of paragraph 121 of the Seventh Affirmative Defense.
122. AstraZeneca denies the allegations of paragraph 122 of the Seventh Affirmative Defense.
123. AstraZeneca denies the allegations of paragraph 123 of the Seventh Affirmative Defense.

124. AstraZeneca denies the allegations of paragraph 124 of the Seventh Affirmative Defense.
125. AstraZeneca denies the allegations of paragraph 125 of the Seventh Affirmative Defense.
126. AstraZeneca denies the allegations of paragraph 126 of the Seventh Affirmative Defense.
127. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 127 of the Seventh Affirmative Defense.
128. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca further admits that Donald Bird signed the Second IDS and submitted it to the PTO. AstraZeneca denies the remaining allegations of paragraph 128 of the Seventh Affirmative Defense.
129. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 129 of the Seventh Affirmative Defense.
130. AstraZeneca admits that Sagent attaches as Exhibits 65 and 66 copies of Plaintiff's supplemental interrogatory responses and further states that those responses speaks for themselves.

131. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca denies the remaining allegations of paragraph 131 of the Seventh Affirmative Defense.
132. AstraZeneca denies the allegations of paragraph 132 of the Seventh Affirmative Defense.
133. AstraZeneca admits that U.S. Application No. 12/285,887 was filed on October 15, 2008. AstraZeneca denies the remaining allegations of paragraph 133 of the Seventh Affirmative Defense.
134. AstraZeneca denies the allegations of paragraph 134 of the Seventh Affirmative Defense.
135. AstraZeneca admits that the Second IDS was submitted to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’887 application. AstraZeneca denies the remaining allegations of paragraph 135 of the Seventh Affirmative Defense.
136. AstraZeneca admits that the 1998 McLeskey Publication and its alleged relevance to one or more of the patents-in-suit was first called to the attention of AstraZeneca by Teva in the Notice Letter dated November 25, 2009 and sent to AstraZeneca by Teva. AstraZeneca further admits that it filed suit for patent infringement against Teva following receipt of the Notice Letter. AstraZeneca

denies the remaining allegations of paragraph 136 of the Seventh Affirmative Defense.

137. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this reference. AstraZeneca denies the remaining allegations of paragraph 137 of the Seventh Affirmative Defense.

138. AstraZeneca admits that it first learned of the 1998 McLeskey Publication and its alleged relevance to one or more of the patents-in-suit when it was called to the attention of AstraZeneca by Teva in the Notice Letter dated November 25, 2009, and AstraZeneca thereafter disclosed the 1998 McLeskey Publication to the PTO. AstraZeneca denies the remaining allegations of paragraph 138 of the Seventh Affirmative Defense.

139. AstraZeneca admits that on or about May 27, 2011 it retained new outside prosecution counsel, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, to handle prosecution of the patents-in-suit. AstraZeneca denies the remaining allegations of paragraph 139 of the Seventh Affirmative Defense.

140. AstraZeneca admits that Allen Giles, as in-house counsel, communicated with outside patent prosecution counsel.

AstraZeneca denies the remaining allegations of paragraph 140 of the Seventh Affirmative Defense.

141. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this reference. AstraZeneca further admits that Sagent attaches as Exhibit 68 a document that it alleges to be a copy of an excerpt from the file history for the ’680 patent and further states that the document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 141 of the Seventh Affirmative Defense.
142. AstraZeneca denies the allegations of paragraph 142 of the Seventh Affirmative Defense.
143. Paragraph 143 of the Seventh Affirmative Defense states a legal conclusion to which no response is required. To the extent the paragraph includes any factual allegations, AstraZeneca denies them.
144. AstraZeneca denies the allegations of paragraph 144 of the Seventh Affirmative Defense.
145. AstraZeneca admits that former employees Allen Giles and Andrew Brown were in-house counsel who oversaw the preparation and prosecution of the Patents-in-Suit and foreign

priority applications. AstraZeneca denies the remaining allegations of paragraph 145 of the Seventh Affirmative Defense.

146. AstraZeneca admits that it has asserted the attorney-client privilege as to the documents identified on its privilege log produced in this litigation. AstraZeneca further admits that Allen Giles, as in-house counsel, communicated with outside patent prosecution counsel. AstraZeneca denies the allegations of paragraph 146 of the Seventh Affirmative Defense.

147. AstraZeneca states that the January 17, 2012 Amendment speaks for itself and denies the remaining allegations of paragraph 147 of the Seventh Affirmative Defense.

148. AstraZeneca admits that Sagent attaches as Exhibit 70 a document that it alleges to be a copy of the January 13, 2012 Sawchuk Declaration and further states that the document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 148 of the Seventh Affirmative Defense.

149. AstraZeneca denies the allegations of paragraph 149 of the Seventh Affirmative Defense.

150. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 150 of the Seventh Affirmative Defense and therefore denies them.

151. AstraZeneca admits that Sagent attaches as Exhibit 33 a document that it alleges to be a copy of a Service Sample Req. and further

states that the paragraph mischaracterizes the documents to which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 151 of the Seventh Affirmative Defense.

152. AstraZeneca admits that Sagent attaches as Exhibit 72 a document that it alleges to be an excerpt of the Faslodex NDA and further states that the paragraph mischaracterizes the documents to which it refers, which document speaks for itself. AstraZeneca denies the remaining allegations of paragraph 152 of the Seventh Affirmative Defense.

153. AstraZeneca admits that the January 17, 2012 Amendment and the January 12, 2012 Sawchuk Declaration were submitted to the PTO in response to a PTO Office Action in which certain then-pending claims were rejected in view of McLeskey. AstraZeneca denies the remaining allegations of paragraph 153 of the Seventh Affirmative Defense.

154. AstraZeneca denies the allegations of paragraph 154 of the Seventh Affirmative Defense.

155. AstraZeneca admits that former employees Allen Giles and Andrew Brown were in-house counsel who oversaw the preparation and prosecution of the Patents-in-Suit and foreign priority applications. AstraZeneca denies the remaining allegations of paragraph 155 of the Seventh Affirmative Defense.

156. AstraZeneca denies the allegations of paragraph 156 of the Seventh Affirmative Defense.
157. AstraZeneca admits that U.S. Application No. 13/602,667 was filed on September 4, 2012, and issued as the '139 Patent. AstraZeneca denies the remaining allegations of paragraph 157 of the Seventh Affirmative Defense.
158. AstraZeneca denies the allegations of paragraph 158 of the Seventh Affirmative Defense.
159. AstraZeneca admits that some of the then-pending claims of the '667 Application initially received a non-final double-patenting rejection from the PTO on January 3, 2013. AstraZeneca denies the remaining allegations of paragraph 159 of the Seventh Affirmative Defense.
160. AstraZeneca admits that former AstraZeneca in-house counsel Allen Giles signed a Terminal Disclaimer dated February 11, 2013, and that this Terminal Disclaimer was submitted in response to a double-patenting rejection. AstraZeneca denies the remaining allegations of paragraph 160.

48. Paragraph 48 states a legal conclusion to which no response is required.

49. AstraZeneca denies the allegations of Paragraph 49.

50. AstraZeneca admits that former employees Allen Giles and Andrew

Brown were in-house counsel who oversaw the preparation and prosecution of the Patents-in-

Suit and foreign priority applications. AstraZeneca denies the remaining allegations of Paragraph 50.

51. AstraZeneca denies the allegations of Paragraph 51.

52. AstraZeneca admits that no reference before the PTO, *including* the 1998 McLeskey Publication, disclosed the Claimed 10/10/15 Formulation. AstraZeneca denies the remaining allegations of Paragraph 52.

53. AstraZeneca denies the allegations of Paragraph 53.

54. AstraZeneca admits the allegations of Paragraph 54.

55. AstraZeneca denies the allegations of Paragraph 55.

56. AstraZeneca denies the allegations of Paragraph 56.

57. AstraZeneca admits the allegations of Paragraph 57.

58. AstraZeneca admits the allegations of Paragraph 58.

59. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this reference. AstraZeneca denies the remaining allegations of Paragraph 59.

60. AstraZeneca denies the allegations of Paragraph 60.

61. AstraZeneca denies the allegations of Paragraph 61.

62. AstraZeneca denies the allegations of Paragraph 62.

63. AstraZeneca denies the allegations of Paragraph 63.

64. AstraZeneca denies the allegations of Paragraph 64. To the extent Paragraph 64 states a legal conclusion, no response is required.

65. AstraZeneca denies the allegations of Paragraph 65.

66. AstraZeneca denies the allegations of Paragraph 66.

67. AstraZeneca denies the allegations of Paragraph 67. To the extent Paragraph 67 states a legal conclusion, no response is required.

68. AstraZeneca denies the allegations of Paragraph 68.

69. AstraZeneca denies the allegations of Paragraph 69. To the extent Paragraph 69 states a legal conclusion, no response is required.

70. AstraZeneca denies the allegations of Paragraph 70.

COUNT X

(U.S. Patent No. 7,456,160 Is Not Unenforceable)

71. AstraZeneca restates and incorporates by reference its responses to the foregoing Paragraphs 1-70 and each of paragraphs 1-160 of Sagent's Seventh Affirmative Defense as if fully stated herein.

72. Paragraph 72 states a legal conclusion to which no response is required.

73. AstraZeneca denies the allegations of Paragraph 73.

74. AstraZeneca admits that former employees Allen Giles and Andrew Brown were in-house counsel who oversaw the preparation and prosecution of the Patents-in-Suit and foreign priority applications. AstraZeneca denies the remaining allegations of Paragraph 74.

75. AstraZeneca denies the allegations of Paragraph 75.

76. AstraZeneca admits that no reference before the PTO, *including* the 1998 McLeskey Publication, disclosed the Claimed 10/10/15 Formulation. AstraZeneca denies the remaining allegations of Paragraph 76.

77. AstraZeneca denies the allegations of Paragraph 77.

78. AstraZeneca admits the allegations of Paragraph 78.

79. AstraZeneca admits the allegations of Paragraph 79.

80. AstraZeneca admits the allegations of Paragraph 80.

81. AstraZeneca denies the allegations of Paragraph 81.

82. AstraZeneca denies the allegations of Paragraph 82.

83. AstraZeneca admits the allegations of Paragraph 83.

84. AstraZeneca admits the allegations of Paragraph 84.

85. AstraZeneca admits that the 1998 McLeskey Publication was disclosed to and considered by the U.S. Patent and Trademark Office (“PTO”) in connection with the prosecution of the ’680 and ’139 patents and those patents were granted by the PTO over this reference. AstraZeneca denies the remaining allegations of Paragraph 85.

86. AstraZeneca denies the allegations of Paragraph 86.

87. AstraZeneca denies the allegations of Paragraph 87.

88. AstraZeneca denies the allegations of Paragraph 88.

89. AstraZeneca denies the allegations of Paragraph 89.

90. AstraZeneca denies the allegations of Paragraph 90.

91. AstraZeneca denies the allegations of Paragraph 91. To the extent Paragraph 91 states a legal conclusion, no response is required.

92. AstraZeneca denies the allegations of Paragraph 92.

93. AstraZeneca denies the allegations of Paragraph 93. To the extent Paragraph 93 states a legal conclusion, no response is required.

94. AstraZeneca denies the allegations of Paragraph 94.

95. AstraZeneca denies the allegations of Paragraph 95. To the extent Paragraph 95 states a legal conclusion, no response is required

96. AstraZeneca denies the allegations of Paragraph 96.

COUNT XI

(U.S. Patent No. 8,329,680 Is Not Unenforceable)

97. AstraZeneca restates and incorporates by reference its responses to the foregoing Paragraphs 1-96 and each of paragraphs 1-160 of Sagent's Seventh Affirmative Defense as if fully stated herein.

98. Paragraph 98 states a legal conclusion to which no response is required.

99. AstraZeneca denies the allegations of Paragraph 99.

100. Paragraph 100 states a legal conclusion to which no response is required.

101. AstraZeneca admits the allegations of Paragraph 101.

102. AstraZeneca admits that there are similarities in the subject matter of the Patents-in-Suit. AstraZeneca denies the remaining allegations of Paragraph 102.

103. AstraZeneca denies the allegations of Paragraph 103 and restates and incorporates by reference its responses to Paragraphs 47-96.

104. AstraZeneca admits that former employees Allen Giles and Andrew Brown were in-house counsel who oversaw the preparation and prosecution of the Patents-in-Suit and foreign priority applications. AstraZeneca denies the remaining allegations of Paragraph 104.

105. AstraZeneca denies the allegations of Paragraph 105.

106. AstraZeneca denies the allegations of Paragraph 106.

107. AstraZeneca denies the allegations of Paragraph 107. To the extent Paragraph 107 states a legal conclusion, no response is required.

108. AstraZeneca denies the allegations of Paragraph 108.

109. AstraZeneca denies the allegations of Paragraph 109.

110. AstraZeneca denies the allegations of Paragraph 110.

111. AstraZeneca denies the allegations of Paragraph 111.

112. AstraZeneca denies the allegations of Paragraph 112.

113. AstraZeneca denies the allegations of Paragraph 113.

114. AstraZeneca admits the allegations of Paragraph 114.

115. AstraZeneca denies the allegations of Paragraph 115.

116. AstraZeneca denies the allegations of Paragraph 116.

117. AstraZeneca denies the allegations of Paragraph 117.

118. AstraZeneca denies the allegations of Paragraph 118. To the extent Paragraph 118 states a legal conclusion, no response is required.

119. AstraZeneca denies the allegations of Paragraph 119.

120. AstraZeneca denies the allegations of Paragraph 120. To the extent Paragraph 120 states a legal conclusion, no response is required.

121. AstraZeneca denies the allegations of Paragraph 121.

COUNT XII

(U.S. Patent No. 8,466,139 Is Not Unenforceable)

122. AstraZeneca restates and incorporates by reference its responses to the foregoing Paragraphs 1-121 and each of paragraphs 1-160 of Sagent's Seventh Affirmative Defense as if fully stated herein.

123. Paragraph 123 states a legal conclusion to which no response is required.

124. AstraZeneca denies the allegations of Paragraph 124.

125. Paragraph 125 states a legal conclusion to which no response is required.

126. AstraZeneca denies the allegations of Paragraph 126.

127. AstraZeneca admits that there are similarities in the subject matter of the Patents-in-Suit. AstraZeneca denies the remaining allegations of Paragraph 127.

128. AstraZeneca denies the allegations of Paragraph 128 and restates and incorporates by reference its responses to Paragraphs 47-121.

PRAYER FOR RELIEF

AstraZeneca denies that Sagent is entitled to the relief requested, or any other relief.

AstraZeneca's Prayer for Relief

WHEREFORE, AstraZeneca respectfully requests the following relief:

(1) A dismissal of all counterclaims as to the '160 patent due to a lack of subject matter jurisdiction;

(2) A judgment dismissing with prejudice Sagent's Counterclaims and each Request for Relief contained therein;

(3) A finding that this is an exceptional case, and an award of attorneys' fees to AstraZeneca, in accordance with 35 U.S.C. § 285;

(4) A finding that counsel for Sagent are liable for excessive costs, and an award of excess costs, expenses, and attorneys' fees to AstraZeneca, in accordance with 28 U.S.C. § 1927;

(5) An award to AstraZeneca of their costs and expenses in this action;

(6) A judgment including each and every Request for Relief sought by AstraZeneca in the Complaint; and

(7) Such further and additional relief as this Court deems just and proper.

Dated: June 20, 2016

Respectfully submitted,

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AstraZeneca AB

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing PLAINTIFFS' ANSWER TO DEFENDANT SAGENT PHARMACEUTICALS, INC.'S COUNTERCLAIMS were caused to be served on June 20, 2016 via email and/or the ECF system upon all counsel of record.

By: s/John E. Flaherty
John E. Flaherty